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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,557

07/29/2003

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59659 (71970)

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21874 7590 02/13/2007  
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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/630,557

**Applicant(s)**

YOUNG ET AL.

**Examiner**

**Susan T. Tran**

## Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Grimmett et al. WO 95/28148.

Grimmett discloses a pharmaceutical formulation comprising a core containing clavulanate, a coating over the core, a casing layer containing amoxicillin, and an over coating layer (Fig. 1; abstract; and page 2, lines 1-8, 30-31; and page 5). The ratios of amoxicillin and clavulanate are between 30:1 to 1:1 and 12:1 to 2:1 (page 2, lines 9-11). Grimmett further discloses a process for preparing the formulation comprising compressing the core, coating the core, introducing the coated core to in a mass of the granulated casing materials (page 3, lines 13-21; page 4, lines 32 through page 5, lines 1-24).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebbers et al. WO 95/20946, in view of Faour et al. US 6,004,582.

Ebbers teaches a bilayered tablet comprising a first layer includes amoxicillin and/or clavulanate, and a second layer includes amoxicillin and/or clavulanate (abstract). Ebbers further teaches it is desirable to prepare tablet with one layer containing amoxicillin without clavulanate and the other layer may contain clavulanate without amoxicillin (page 2, lines 25-27; page 7, lines 36-38). The ratios of amoxicillin and clavulanate are between 30:1 to 1:1 and 8:1 to 1:1 (page 2, lines 13-17). The tablet further comprises a barrier layer between the first and second layer (page 3, lines 36-37). Ebbers also teaches the tablet is covered with a protective coating layer (page 6, lines 26-33). The tablet is prepared by known compression tableting techniques (page 9, lines 31 through page 10, lines 1-38).

It is noted that Ebbers does not explicitly teach tablet having a core and an outer layer. Faour teaches a multi-layered device comprising a core containing first active agent, and coating layer surrounding the core comprising second active agent that is different from the first active agent (Fig. 2; column 6, lines 11-53; and column 9, lines 29-37). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the layer tablet of Ebbers using the core layer tablet in view of the teachings of Faour, because Faour teaches layer tablets that provide controlled release of first active agent in the core and an immediate release of a second active layer surrounding the core, because Faour teaches an improved multi-layer tablet that overcomes many of the disadvantages in the related prior art devices (column 3,

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lines 30-48), and because Ebbers teaches the desirability of obtaining layer tablets to control the release rates of two different active agents.

### ***Response to Arguments***

Applicant's arguments filed 11/06/06 have been fully considered but they are not persuasive.

Applicant argues that Grimmatt teaches amoxicillin should be present in both, the core and the casing layer, and clavulanate can be contained in either the core or the casing layer or both. In contrast to Grimmatt, the present invention requires that clavulanate is contained in the core and amoxicillin is contained in the outer layer surrounding the core.

Contrary to the applicant's arguments, applicant's attention is called to page 2, lines 30-31, where Grimmatt specifically discloses "all of the clavulanate contained in the core, with none of the clavulanate contained in the casing layer". Accordingly, Grimmatt teaches the claimed dosage form.

Applicant argues that due consideration and weight must be given to whether or not the prior art exemplifies the claimed invention by working examples.

However, applicant's argument is not persuasive at least for the following reasons:

1) as stated above, Grimmatt clearly discloses a core that contains nothing other than clavulanate, and a casing layer that does not contain any clavulanate;

2) Grimmet is relied upon for the teachings within the four-wall patent, Grimmet cannot be limited to his best mode invention as disclosed in the examples; and

3) the present claims do not preclude the present of other active agents in both the core and the casing layer.

Accordingly, the 102(b) rejection over Grimmett is maintained.

Applicant argues that Ebbers discloses only a simple bi-layered tablet, and does not teach or suggest the "cored tablet" of the present invention. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Faour cannot remedy the deficiencies of Ebbers because Faour teaches the core is separated from the external coating by a water soluble polymer coating comprising poly(vinylpyrrolidone)-(vinyl acetate) copolymer.

However, in response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Furthermore, the

transitional language recited in the present claims does not preclude additional coating layer(s).

Accordingly, the 103(a) rejection over Ebbers in view of Faour is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

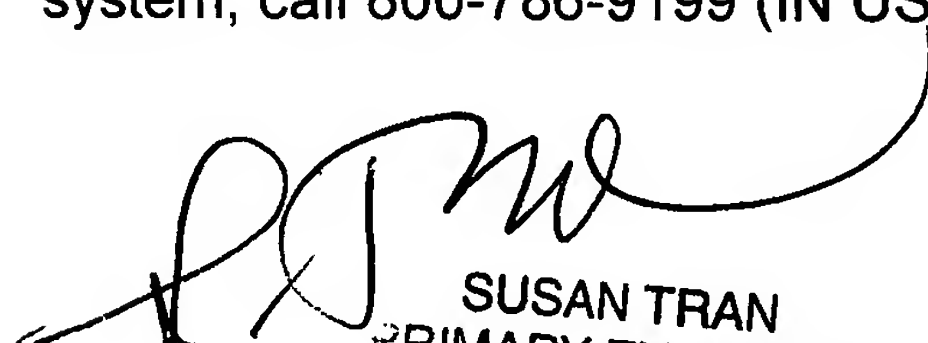
### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SUSAN TRAN  
PRIMARY EXAMINER

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